DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2015

Medtronic, Inc.
Chelsea L. Pioske
Regulatory Affairs Specialist
7611 Northland Dr.
Minneapolis, MN 55428

Re: K150422
Trade/Device Name: EOPA 3D Arterial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 18, 2015
Received: February 19, 2015

Dear Ms. Chelsea Pioske,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150422

Device Name
EOPA 3D Arterial Cannula

Indications for Use *(Describe)*
These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: February 18, 2015

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Chelsea Pioske
Regulatory Affairs Specialist
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Alternate Contact:
Sue Fidler
Senior Regulatory Affairs Manager
Medtronic Perfusion Systems
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Fax: 763.367.8360
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Trade Name: EOPA 3D® Arterial Cannula
Classification Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulation Number: 21 CFR 870.4210
Product Classification: Class II
Product Code: DWF

Name of Predicate Device: EOPA 3D Arterial Cannula, Models 78220,78222,78320,78322

Device Description:
The EOPA 3D® Arterial Cannula consists of a flexible, thin wall, wirewound body with a tapered distal tip. The tip features depth markings and an adjustable radiopaque suture ring to indicate insertion depth. The proximal end of the cannula terminates in a vented or non-vented connector. An obturator is provided to facilitate cannula insertion and priming. Multiple depth markings, catalog code, and French size are printed on the cannula body. The EOPA 3D® Arterial Cannula is sterile, nonpyrogenic, and single use.

Indications for Use:
These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Contraindications:
The device is not intended for use except as indicated above.

Comparison to Predicate Devices:
A comparison of the EOPA 3D® Arterial Cannula to the predicate device (the EOPA 3D® Arterial Cannula) indicates the following similarities:

- Intended Use: The intended use is the same as predicate devices.
- Design: The overall design is the same as the predicate.
- Materials: The base material types used are the same as the predicate. The proposed material formulation change of the cap remains polypropylene.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance is substantially equivalent to the predicate device.

Summary of Testing
Testing has demonstrated that the EOPA 3D Arterial Cannula is substantially equivalent to the predicate.

The following tests were conducted to demonstrate substantial equivalence of the proposed cap (with alternate material formulation) to the current cap:

Component	Base Material Changes	Verification/Validation	Results
Luer Cap	Current: Polypropylene Proposed: Polypropylene	Liquid Leakage	Pass
		Separation Force	Pass
		Unscrewing Torque	Pass
		Resistance to Overriding	Pass
		Stress Cracking	Pass
		Cytotoxicity	Pass
		Sensitization	Pass
		Irritation/Intracutaneous	Pass
		Acute Systemic Toxicity	Pass
		Hemocompatibility	Pass

Conclusion:
The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the EOPA 3D® Arterial Cannula is substantially equivalent to the legally marketed predicate device, the EOPA 3D® Arterial Cannula (K061254).